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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------|------------------|
| 09/920,215   | 08/01/2001  | David Clive Blakemore | A0000303-01-CA      | 5314             |
| 7590   | 10/19/2004  |                       | EXAMINER            |                  |
| Charles W. Ashbrook<br>Warner-Lambert Company<br>2800 Plymouth Road<br>Ann Arbor, MI 48105 |             |                       | REYES, HECTOR M     |                  |
|  |             |                       | ART UNIT            | PAPER NUMBER     |
|  |             |                       | 1625                |                  |

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                  |
|------------------------------|-----------------|------------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)     |
|                              | 09/920,215      | BLAKEMORE ET AL. |
|                              | Examiner        | Art Unit         |
|                              | Hector M Reyes  | 1625             |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1 to 33 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 21 is/are allowed.

6) Claim(s) 1-8, 11-18, 20 and 24 to 33 is/are rejected.

7) Claim(s) 9,10,19 22-23 is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- 1) Certified copies of the priority documents have been received.
- 2) Certified copies of the priority documents have been received in Application No. \_\_\_\_.
- 3) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

**Priority Paper**

Examiner acknowledges Applicant's claim of Priority of application UK 0018828.4 date: 08/01/2000. Certified copy of such Application is not found on the record.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The definition of the claimed compounds of formula III embraced ALL compounds wherein the variable Q "is a labile amine or amide-forming organic group that becomes removed in the human or animal body" and also the compounds wherein the variable R4 "is a labile ester-forming group selected from substituted and unsubstituted C1-C6 alkyl, benzyl and phenyl groups that becomes removed in the human or animal body". While such definition is extensively broad, the specification only present three examples of such compounds and therefore there is no support in the specification directed to enable any person skill in the art to prepare the extensive and variable family of claimed compounds.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. The phrase " amide-forming organic group that becomes removed in the human or animal body" used to defined variable group Q is not clear because there is no a clear definition of the groups that are embraced by such phrase nor a clear sets of conditions that specifically outline the groups that satisfies such phrase.

Claims 3 and 13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 3 and 13, the phrase "in which R4 is other than hydrogen and is more labile than Q " is not definite because there is no parameters or standards to measure the strength of each group in order to determine which group is more labile than the other. How labile is defined? How it is measure? What are the units of such measurement?

Moreover, even if such determination is clearly established, it is not indicated how "more labile" R4 have to be in comparison with group Q in order to satisfies Applicant broad definition.

Claims 5, 6, 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Such claims included all compounds that contain a Q variable group that can be removed by hydrolysis under physiological conditions or enzymatically under physiological conditions. However, the specification only provides support for the preparation of a very limited number of such compounds.

Claims 5, 6, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In such claims, the compound of claim 1 is define by reference to a desirable characteristic or property, namely, having a labile bonding group which can be removed: hydrolytically under physiological conditions or enzymatically, however, there is not clear way to know which compounds are embraced by such definition and moreover a clear sets of conditions that specifically outline the groups that satisfies such definition. What are the specific conditions to hydrolyze such groups? What are the physiological conditions required? Which are the enzymes required in such process?

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7, 8, 13, 14, 17, 18 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Brenner et al, Helvetica Chimica Acta, vol. 82, 1991, pages 2365-2379. Brenner discloses the enantioselective preparation of alpha amino acids, among them, alpha amino butyric acids derivatives, analogs of alpha aminobutyric acid (GABA), see for example, Scheme 5, page 2369, and more particularly, compound 7 in the same Scheme 5: Hexanoic Acid, 3-[[[(1, 1-dimethylethoxy)carbonyl]amino]methyl]-5-methyl-methyl ester.

Brenner discloses that unnatural gamma amino acids have found pharmaceutical application as GABA analogues (see page 2365first paragraph).

Claims 1, 2, 7, 8, 11, 12, 17, 18, 24, 25, 26, 27, 28, 29, 30, 31, 32 and 33are rejected under 35 U.S.C. 102(b) as being anticipated by Belliotti et al, WO9931074.

Belliotti discloses the preparation of novel amines as pharmaceutical agents. Among the compounds prepared is Boc-isobutyl-GABA, see compound B and its preparatory procedure as described in page 19.

Belliotti discloses the pharmaceutical composition prepared from the compounds of its invention in order to be use as agents in the treatment of:

- Epilepsy,
- Faintness attacks,
- Hypokinesia,
- Cranial disorders,
- Neurodegenerative disorders,
- Depression,
- Anxiety,
- Panic,
- Neuropathological disorders,
- Inflammatory diseases and
- Gastrointestinal disorders.

(see page 2, 8, and 14-16).

Claims 1, 2, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Picard et al, WO 98/09957.

Picard discloses the preparation of compounds for and a method of inhibiting matrix metalloproteinases. Among the compounds prepared by Picard is 2(S)-3-[(Dibenzofuran-2-sulfonylamino)-methyl]-5-methyl-hexanoic acid, as described in page 35.

### **CLAIMS OBJECTIONS**

Claims 9, 10, 19, 20 and 22 are objected because such claims depend directly or indirectly of rejected claim 1.

### **ALLOWABLE SUBJECT MATTER**

Claim 21 is drawn to specific compounds and pharmaceutical acceptable salts. Such compounds were not found disclosed or suggested in the prior art.

### **CONCLUSION**

Any inquiry concerning this communication should be directed to Hector M. Reyes whose telephone number is (703) 605-1153. The examiner can normally be reached on Monday to Friday from 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner 's supervisor, Allan Rotman can be reached on (703) 308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or for regular communication and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.